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10/714,047	11/13/2003	Gregor Dudziak	100717-606 / Bayer 10267	3213
27386	7590	06/03/2008	EXAMINER	
NORRIS, MC LAUGHLIN & MARCUS, P.A.			OLSEN, KAJ K	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/714,047	Applicant(s) DUDZIAK ET AL.
	Examiner KAJ K. OLSEN	Art Unit 1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 March 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1-18 is/are allowed.
- 6) Claim(s) 19 and 22-26 is/are rejected.
- 7) Claim(s) 20, 21 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1668)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Objections

1. The outstanding claim objections have been withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 19, 22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez et al (USP 4,758,320).

4. As to Claim 19, Sanchez et al. disclose an appliance for membrane electrophoresis comprising an at least quadripartite separation chamber (Figure 1) having a diluate space, a concentrate space (4, 5), an anode space, and a cathode space (8, 9), having electrodes as the anode and cathode (col. 5, ll. 9-11); the spaces separated by porous membranes (2, 3), especially ultrafiltration or microfiltration membranes (col. 3, ll. 47-53); feed lines and discharge lines for the diluate, concentrate, and electrode rinsing solution (Figure 1); and a pressure difference of at least 3 kPa between the diluate and concentrate spaces (col. 3, ll. 43-46). The cathode and anode spaces are separated from the dilute and concentrate spaces by membranes 14 and 15, which are disclosed as being only ion-permeable. Because these

membranes are only ion-permeable and are disclosed as not even permitting solvent permeability (col. 6, ll. 48-64), they read on the applicant's term "restriction membrane" and they would have a substantially lower cutoff point than the ultrafiltration membranes because the ultrafiltration and microfiltration membranes are porous enough to permit molecules less than 200 Angstrom or 10 microns to pass whereas the restriction membranes (14, 15) would permit only much smaller ions. See col. 3, ll. 47-53.

5. As to Claim 22, Sanchez et al. disclose the feed and discharge lines for the diluate, concentrate, and electrode rinsing solution are arranged in separate circuits (Figure 1).

6. As to Claim 24, Sanchez et al. disclose a membrane pore size from 1 to 1000 nm (col. 3, ll. 46-53).

7. As to Claim 25, Sanchez et al. disclose the membranes formed of polyacrylonitrile (col. 4, ll. 48-55).

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 19, 22, 24, and 25 in the alternative are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez in view of Ogle et al (US 2003/0019753 A1).

10. In the rejection above, Sanchez was interpreted as meeting the new limitations regarding the restriction membrane cutoff points because the ion permeable membranes of Sanchez would clearly have cutoff points much lower than the cutoff points for the ultrafiltration or microfiltration membranes. However, even if the ion-permeable membranes of Sanchez were

interpreted as not meeting this new limitation, Ogle teaches the use of restriction membranes between the anode and cathodes and the other chambers of the device that have cutoff points that are clearly smaller the cutoff points for the remaining membranes in the electrophoretic chamber. See paragraph 0165 where the restriction membranes have a cutoff of 500 dalton while the remaining membranes include cutoffs of 100,000 to a 1,000,000 dalton. Because only ion-transfer is needed through the membranes separating the anode and cathode spaces from the concentrate and dilute spaces of Sanchez (col. 6, ll. 48-53), one possessing ordinary skill in the art at the time the invention was being made would have recognized that ion-permeable membranes having a lower cutoff point than the remaining membranes (as taught by Ogle) would have yielded the predictable result of having the anode and cathodes spaces in electrical connection with the dilute and concentration spaces without a large degree of macromolecular transfer.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez or Sanchez in view of Ogle, and in further view of Gritzner (USP 4,043,895).

6. This claim remains rejected for the reasons set forth in the previous office action.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez or Sanchez in view of Ogle, and in further view of Ahlgreen et al (USP 4,043,896).

8. This claim remains rejected for the reasons set forth in the previous office action.

Response to Arguments

9. Applicant's arguments filed 3-6-2008 have been fully considered but are not persuasive. Applicant urges that Sanchez has an uneven number of compartments and wouldn't read on the concept of the separation chamber being formed by pairs of diluate and concentrate spaces. Although the examiner is in agreement that Sanchez has an uneven number of compartments, the examiner disagrees that this reads free of the claimed invention. In particular, claim 19 is constructed with open language (i.e. the appliance is "comprising" the set forth features). Hence, if Sanchez comprises at least one pair of diluate and concentrate spaces (as all the embodiments of fig. 1-4 have), then it meets the claims even if the Sanchez embodiments of fig. 1, 3, and 4 contain an additional diluate space. There is nothing in claim 19 that limits the number of spaces to even numbers, only that there needs to be at least one pair of diluate and concentrate spaces.

10. Applicant also urges that there is nothing in Sanchez to teach or suggest the use of restriction membranes to delimit the pair of diluate/concentrate spaces from each other. However, for claim 19, the use of restriction membrane need only be placed between the pairs of diluate and concentrate spaces when there is more than one pair. In particular, claim 19 states "and each pair of diluate and concentrate spaces, *if there be more than one*, being separated from the others by restriction membranes" (emphasis added). Looking at the embodiment of fig. 4 of Sanchez, it only comprises a single pair of diluate and concentrate spaces (4c, 5c) with an additional unpaired diluate space 4'c. For an embodiment like this fig. 4, it is unnecessary to place a restriction membrane between the difference pairs of diluate and concentrate spaces because there is only one pair of spaces. Applicant's argument here however is persuasive for the case of claim 20 where applicant specifies that there has to be a plurality of pairs of diluate

and concentrate spaces. Because Sanchez does not teach nor suggest the use of restriction membranes between each pair of diluate and concentrate spaces, claim 20 is free of the prior art.

11. With respect to the rejections relying on Ogle, applicant urges that the restriction membranes of Ogle are not disclosed as serving any other purpose than restricting convective transport. The examiner believes this to be incorrect. Ogle teaches the use of much more restrictive membrane (5000 dalton cutoff) between the anode and cathode spaces and the remainder of the chambers than between any of the other chambers that rely on either 100,000 and 1,000,000 dalton cutoffs. Ogle further teaches that the desired IgG is trapped by the 100,000, but not the 1,000,000 whereas the other proteins can get through the 100,000, but are trapped in spaces 1, 4, 7, and 10. See paragraphs 0165-0167. The reason they are trapped in these spaces and do not instead proceed into the cathode or anode spaces is clearly because of the highly restrictive 5000 dalton cutoff membrane separating these spaces from both the anode and cathode. Hence, one possessing ordinary skill in the art would clearly recognize that Ogle is teaching the use of restriction membranes separating the anode and cathode so that the various species being separated by membrane electrophoresis device do not proceed into the anode and cathode spaces of the device.

12. Applicant's arguments concerning Gritzner appear to stem from the applicant's perceived failings of the earlier Sanchez or Sanchez in view of Ogle rejections. Because these earlier arguments were unpersuasive (see above), these further arguments are similarly unpersuasive.

Allowable Subject Matter

13. Claims 1-18 are allowed.

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14. Claims 20 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. With respect to the allowable subject matter of claims 1-18, see paragraph 10 from the 5/24/2007 office action. With respect to the allowable subject matter of claims 20 and 21, see the discussion in the Response to Arguments above.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
June 3, 2008